

Section 6- 510(k) Summary

DEC 17 2009

a. Owner/Company name, address

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b. Contact/Application Correspondent

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c. Date prepared

October 5, 2009

d. Name of device

Trade Name:	SUPERCATH 5
Common Name:	Intravascular Catheter
Classification Name:	Catheter, Intravascular, Therapeutic, Short-term less than 30 days
Classification Regulation:	21 CFR 880.5200

e. Predicate devices

The SUPERCATH 5 is substantially equivalent to the following legally marketed devices:

510(k): k013800
Trade name: Insyte Autoguard™ IV Catheter
Product code: FOZ

The same trade name with the device for the application;

510(k): k081953
Trade name: SUPERCATH 5
Product code: FOZ

f. Description of the device

The device is an intravascular catheter known by the trade name SUPERCATH 5 (PROPOSED). It is available in four models, with a check valve, with a side-notch needle, with a check valve and a side-notch needle, and without both a check valve and a notched needle. (See below Figure 1).

The SUPERCATH 5 (PROPOSED) is intended to access a vein or artery and to administer fluids. The SUPERCATH 5 (PROPOSED) is designed for single use and for short-term use (less than 30 days), is designed to minimize inadvertent needlesticks and to reduce accidental needlesticks.

The SUPERCATH 5 (PROPOSED) catheter hub has a built-in check valve which together with the healthcare professional's finger pressure on the blood vessel, assists to reduce blood flashback when the metallic introducer needle is withdrawn following blood vessel puncture. The built-in check valve is not intended to stop bleeding completely. Pressing the button on the needle hub activates the coiled spring in the hub, retracting the metallic introducer needle into the needle hub.

The SUPERCATH 5 (PROPOSED) introducer needle has a side-notch to provide rapid visual confirmation of vessel entry. When the introducer needle is inserted into the vein, blood flows up and through the side-notch and returns down along the inside of the catheter tube.

The SUPERCATH 5 (PROPOSED) is available in 14G, 16G, 18G, 20G, 22G and 24G.

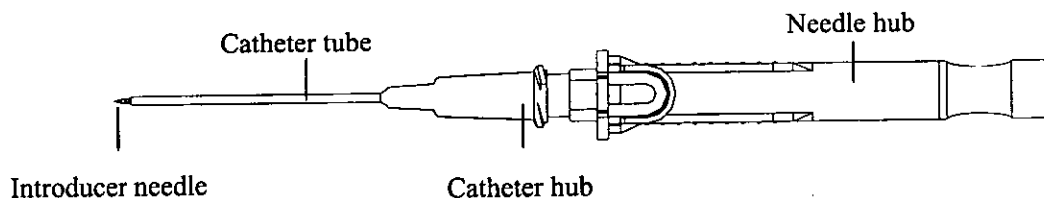


Figure 1. SUPERCATH 5

g. Modification description

The SUPERCATH 5 (PROPOSED) contains the following modifications as compared to the SUPERCATH 5 (k081953):

1. Addition of 14G and 16G sizes.
2. Modify 22G and 24G introducer needle to include a side-notch to provide rapid visual confirmation of vessel entry.

To evaluate the any effects of the above changes on safety and effectiveness, risk analysis (see Section 18 Risk Analysis) and performance testing (see Section 21 Performance Testing – Bench) were performed. In conclusion the risk analysis and performance testing demonstrated that the above listed modifications did not raise any new safety or effectiveness concerns.

h. Indications for Use**Indication for Use**

The SUPERCATH 5 is intended to access a vein or artery and to administer fluids. The SUPERCATH 5 is designed for single use and for short-term use (less than 30 days), is designed to minimize inadvertent needlesticks and to reduce accidental needlesticks.

i. Statement of substantial equivalence

The characteristics of the SUPERCATH 5 (PROPOSED) are similar to those of the predicate devices described in Item e above. The similarities are:

- Same Intended Use
- Same Catheter Material (Polyurethane)
- Radiopaque
- Flashback Visualization
- Needle Stick Injury Prevention Feature
- Check Valve
- Ethylene Oxide Sterilized
- Single Sterile Wrapped
- Multiple Gauge Sizes and Needle Lengths

Table 1. Comparison of Factor/Component

Factor/Component	SUPERCATH 5 (PROPOSED)	Insyte Autoguard™ IV Catheter (k013800)	SUPERCATH 5 (k081953)
Same Intended Use	Yes	Yes	Yes
Polyurethane Catheter	Yes	Yes	Yes
Radiopaque Catheter	Yes	Yes	Yes
Flashback Visualization	Yes	Yes	Yes
Needle Stick Injury Prevention Feature	Yes	Yes	Yes
Check Valve	Yes	No	Yes
Ethylene Oxide Sterilized	Yes	Yes	Yes
Single Sterile Wrapped	Yes	Yes	Yes
Multiple gauge sizes and needle lengths	Yes	Yes	Yes
Side-Notch needle	Yes	Yes	No

The SUPERCATH 5 (PROPOSED) has the same intended use and similar technological characteristics as the “Insyte Autoguard™ IV Catheter” (k013800) and the “SUPERCATH 5” (k081953). Similar components and materials are used in the SUPERCATH 5 (PROPOSED) as in the “SUPERCATH 5” (k081953).

j. Risk Analysis

The SUPERCATH 5 (PROPOSED) was evaluated in accordance with ISO14971:2007. The risk management of the device was deemed satisfactory. See Section 18 Risk Analysis.

k. Bench Testing

Bench tests were performed to ensure the safety and effectiveness of the SUPERCATH 5 (PROPOSED), verify conformity to the recognized standards and demonstrate substantial equivalence to the predicate device(s). All SUPERCATH 5 (PROPOSED) samples were compliant with the ISO and USP standards and demonstrated substantial equivalence to the predicate device(s).

l. Simulated Clinical Use

In accordance with FDA’s guidance “Medical Devices with Sharps Injury Prevention Features”, Document issued on: August 9, 2005, the sharp needle injury prevention feature of the SUPERCATH 5 (k081953) was tested.

According to the risk analysis (See Section 18 Risk Analysis), the modifications to the SUPERCATH 5 (k081953), of 1) the additional gauge sizes of 14G and 16G and 2) the side-notch on the introducer needle of the 22G and 24G, have no effect on the sharp needle injury prevention feature of the SUPERCATH 5 (PROPOSED). Therefore, Togo Medikit has included the exact same report submitted with the SUPERCATH 5 (k081953). (See Section 23 Performance Testing – Simulated Clinical Use.)

SUPERCATH 5
PREMARKET NOTIFICATION 510(k)

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The purpose of the investigation was to test if the sharp needle injury prevention feature of the SUPERCATH 5 (k081953) worked properly under a simulated use clinical environment. As per recommendation under the "Guidance", eight (8) health care professional volunteers who routinely use this type of catheter in their clinical practice were recruited.

The primary evaluation parameter was to test if the metal introducer needle completely retracted into the plastic needle hub after firmly pressing the safety button. This mechanism is the sharp needle injury prevention feature of the SUPERCATH 5 (k081953) (PREDICATE) and the SUPERCATH 5 (PROPOSED).

No failures were observed in over 500 tests, under different test conditions and five (5) different catheter sizes of the SUPERCATH 5 (PREDICATE). Thus, the requirement of statistical significance of the safety feature was confirmed for the sharp needle injury prevention feature of the SUPERCATH 5 (PREDICATE).

Therefore, Togo Medikit believes that the same results apply to the identical safety feature of the SUPERCATH 5 (PROPOSED), since the modifications to the SUPERCATH 5 (k081953), of 1) the additional gauge sizes of 14G and 16G and 2) the side-notch on the introducer needle of the 22G and 24G, have no effect on the sharp needle injury prevention feature of the SUPERCATH 5 (PROPOSED) (See Section 18 Risk Analysis.)

m. Conclusion

Based on the above discussion and enclosed sections regarding substantial equivalence to predicate devices, Togo Medikit concludes that the SUPERCATH 5 (PROPOSED) is substantially equivalent to the "Insyte Autoguard™ IV Catheter" (k013800) and the "SUPERCATH 5" (k081953) and does not raise any new questions regarding safety or effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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C/o Fumiaki Kanai, Ph.D.
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MIC International
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JAPAN

DEC 17 2009

Re: K093546
Trade/Device Name: SUPERCATH 5
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: October 5, 2009
Received: November 17, 2009

Dear Dr. Kanai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

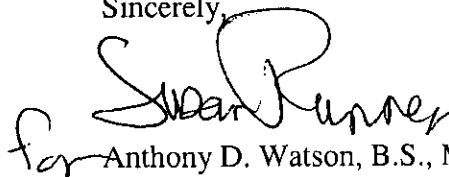
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportAProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

A handwritten signature in black ink, appearing to read "Anthony D. Watson", is written over the typed name.

Anthony D. Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (If known): K093546

Device Name: SUPERCATH 5

Indication for Use

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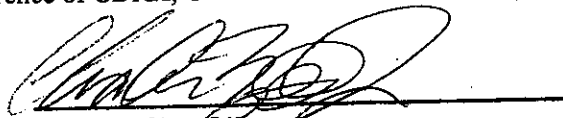
Prescription Use ☒
(Per 21 CFR 801 Subpart D)

AND/OR

Over-the Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093546